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Elaine C. Stracker

PATENT

Attorney's Docket No.: 00029.10CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Rabinowitz et al.
Serial No.: 10/750,303
Filed: 12/30/2003
Title DELIVERY OF ANTIPSYCHOTICS THROUGH AN INHALATION
ROUTE

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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with their continuing duty of disclosure under 37 CFR §§ §1.97, 1.98 and 1.56, Applicants hereby submit for consideration in the above-identified application the enclosed references. The Information Disclosure statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

For the convenience of the Examiner, the references are listed on a PTO Form 1449 (attached) and copies thereof are enclosed. Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

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Elaine C. Stracker J.D., Ph.D., Reg. 43,166

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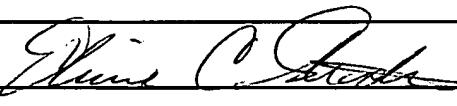
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		Application Number	10/750,303
		Filing Date	12/30/2003
		First Named Inventor	Joshua D. Rabinowitz
		Art Unit	Not yet known
		Examiner Name	To be assigned
Total Number of Pages in This Submission		Attorney Docket Number	00029.10CON

ENCLOSURES (check all that apply)

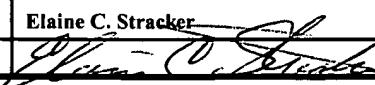
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Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>	Docket Number: 00029.10 CON		Application Number: 10/750,303	
	Applicant: Joshua D. RABINOWITZ et al.			
	Filing Date:	12/30/2003		Group Art Unit:
				Not Yet Known

U.S. PATENT DOCUMENTS

Examiner Initials	Ref No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	09/01/1959	2,902,484	Horclois			
	2.	02/02/1971	3,560,607	Hartley et al.			
	3.	01/15/1980	4,183,912	Rosenthal			
	4.	05/27/1980	Re. 30,285	Babington			
	5.	01/23/1990	4,895,719	Radhakrishnun et al.			
	6.	09/17/1991	5,049,389	Radhakrishnun			
	7.	02/14/1995	5,388,574	Ingebrethsen			
	8.	08/13/1996	5,544,646	Lloyd et al.			
	9.	12/09/1997	5,694,919	Rubsamen et al.			
	10.	04/07/1998	5,735,263	Rubsamen et al.			
	11.	04/14/1998	5,738,865	Baichwal et al.			
	12.	06/02/1998	5,758,637	Ivri et al.			
	13.	06/29/1999	5,915,378	Lloyd et al.			
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	15.	09/28/1999	5,957,124	Lloyd et al.			
	16.	10/05/1999	5,960,792	Lloyd et al.			
	17.	11/30/1999	5,993,805	Sutton et al.			
	18.	03/28/2000	6,041,777	Faithfull et al.			
	19.	04/18/2000	6,051,566	Bianco			
	20.	08/01/2000	6,095,134	Sievers et al.			
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	23.	06/05/2001	6,241,969	Saidi et al.			
	24.	07/03/2001	6,255,334	Sands			
	25.	10/09/2001	6,299,900	Reed, et al.			

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	26.	04/23/2002	6,376,550	Raber et al.			
	27.	07/16/2002	6,420,351	Tsai et al.			
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	35.	08/22/2002	US 2002/0112723	Schuster et al.			
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	37.	01/02/2003	US 2003/0004142	Prior et al.			
	38.	02/13/2003	US2003/0032638	Kim et al.			

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	40.	08/04/2003	10/633,877	Hale et al.			
	41.	12/30/2003	10/749,537	Rabinowitz et al.			
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	53.	01/29/2004	10/768,293	Rabinowitz et al.			
	54.	01/30/2004	10/769,046	Rabinowitz et al.			

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		Filing Date: 12/30/2003		Group Art Unit: Not Yet Known	

	55.	01/30/2004	10/769,051	Rabinowitz et al.			
	56.	01/29/2004	10/769,157	Rabinowitz et al.			
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	58.	02/09/2004	10/775,583	Rabinowitz et al.			
	59.	02/09/2004	10/775,586	Rabinowitz et al.			
	60.	03/03/2004	10/791,915	Hale et al.			
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	81.	01/09/2003	US 2003/0007933	Rabinowitz et al.			
	82.	01/09/2003	US 2003/0007934	Rabinowitz et al.			
	83.	01/16/2003	US 2003/0012737	Rabinowitz et al.			
	84.	01/16/2003	US 2003/0012738	Rabinowitz et al.			

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		Filing Date: 12/30/2003			Group Art Unit: Not Yet Known	

	85.	1/16/2003	US 2003/0012740	Rabinowitz et al.			
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	100.	05/27/2004	US 2004/010148	Hale et al.			
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	102.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
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	111.	07/01/2004	US 2004/0126329	Rabinowitz et al.			
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	113.	07/01/2004	US 2004/0127490	Rabinowitz et al.			
	114.	08/12/2004	US 2004/0156788	Rabinowitz et al.			

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				Filing Date: 12/30/2003	Group Art Unit: Not Yet Known

	115.	08/12/2004	US 2004/0156789	Rabinowitz et al.			
	116.	8/12/2004	US 2004/0156790	Rabinowitz et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	117.	03/14/1990	EP 0 358 114	Europe			
	118.	07/03/2001	EP 1 080 720	Europe			
	119.	08/29/2001	EP 0 606 486	Europe			
	120.	04/11/1996	WO 96/09846	WIPO			
	121.	05/09/1996	WO 96/13161	WIPO			
	122.	05/09/1996	WO 96/13290	WIPO			
	123.	05/09/1996	WO 96/13291	WIPO			
	124.	05/09/1996	WO 96/13292	WIPO			
	125.	10/03/1996	WO 96/30068	WIPO			
	126.	08/07/1997	WO 97/27804	WIPO			
	127.	10/02/1997	WO 97/35562	WIPO			
	128.	05/28/1998	WO 98/22170	WIPO			
	129.	07/23/1998	WO 98/31346	WIPO			
	130.	08/27/1998	WO 98/36651	WIPO			
	131.	04/08/1999	WO 99/16419	WIPO			
	132.	12/16/1999	WO 99/64094	WIPO			
	133.	01/06/2000	WO 00/00176	WIPO			
	134.	01/06/2000	WO 00/00215	WIPO			
	135.	05/18/2000	WO 00/27363	WIPO			
	136.	05/18/2000	WO 00/27359	WIPO			
	137.	05/25/2000	WO 00/29053	WIPO			

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		Filing Date:	12/30/2003	Group Art Unit: Not Yet Known

	138.	09/17/2000	WO 00/47203	WIPO			
	139.	11/02/2000	WO 00/64940	WIPO			
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	142.	12/21/2000	WO 00/76673	WIPO			
	143.	01/25/2001	WO 01/05459	WIPO			
	144.	03/01/2001	WO 01/13957	WIPO			
	145.	06/14/2001	WO 01/41732	WIPO			
	146.	12/20/2001	WO 01/95903	WIPO			
	147.	03/28/2002	WO 02/24158	WIPO			
	148.	03/28/2002	WO 02/24158	WIPO			

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	149.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
	150.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology</i> (Berl). 102:443-450.
	151.	Clark, A. and Byron, P. (1986). "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank.</i> 166:13-24.
	152.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society</i> . 966-974.
	153.	Davies, C.N..et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology</i> . 32(5):591-600.
	154.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology</i> . 93(3): 619-628.
	155.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14 (Table of Contents). pp. v-viii.
	156.	Gonda,I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.

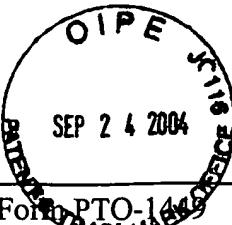
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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 5%;">157.</td><td>Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry & Behavior</i>. 36(1):1-7.</td></tr> <tr><td>158.</td><td>Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 μm," <i>J. Aerosol Sci.</i> 17(5):811-822.</td></tr> <tr><td>159.</td><td>Huizer, H., "Analytical studies on illicit heron. V. Efficacy of volatilization during heroin smoking." <i>Pharmaceutisch Weekblad Scientific Edition</i> (1987). 9(4):203-211.</td></tr> <tr><td>160.</td><td>Hurt, R.D., MD and Robertson, C.R., PhD, (October 1998). "Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial," <i>JAMA</i> 280(13):1173-1181.</td></tr> <tr><td>161.</td><td>Lichtman, A.H. et al. (1996). "Inhalation Exposure to Volatilized Opioids Produces Antinociception in Mice," <i>Journal of Pharmacology and Experimental Therapeutics</i>. 279(1):69-76.</td></tr> <tr><td>162.</td><td>Martin, B.R. and Lue, L.P. (May/June 1989). "Pyrolysis and Volatilization of Cocaine," <i>Journal of Analytical Toxicology</i> 13:158-162.</td></tr> <tr><td>163.</td><td>Mattox, A.J. and Carroll, M.E., (1996). "Smoked heroin self-administration in rhesus monkeys," <i>Psychopharmacology</i>, 125:195-201.</td></tr> <tr><td>164.</td><td>Meng, Y. et al. "Inhalation Studies With Drugs of Abuse," <i>NIDA Research Monograph</i>, (1997) 173:201-224.</td></tr> <tr><td>165.</td><td>Meng, Y., et al. (1999). "Pharmacological effects of methamphetamine and other stimulants via inhalation exposure," <i>Drug and Alcohol Dependence</i>. 53:111-120.</td></tr> <tr><td>166.</td><td>Office Action mailed 8/13/2003 for US application 10/153,313 filed 05/21/2002 "DELIVERY OF BENZODIAZEPINES THROUGH AN INHALATION ROUTE".</td></tr> <tr><td>167.</td><td>Pankow, J.F. et al. (1997). "Conversion of Nicotine in Tobacco Smoke to Its Volatile and Available Free-Base Form Through the Action of Gaseous Ammonia," <i>Environ. Sci. Technol.</i> 31:2428-2433.</td></tr> <tr><td>168.</td><td>Pankow, J. (March 2000). ACS Conference-San Francisco-3/26/00. Chemistry of Tobacco Smoke. pp. 1-8.</td></tr> <tr><td>169.</td><td>Seeman, J. et al. (1999). "The Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," <i>J. Agric. Food Chem.</i> 47(12):5133-5145.</td></tr> <tr><td>170.</td><td>Sekine, H. and Nakahara, Y. (1987). 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		Applicant: Joshua D. RABINOWITZ et al.	
		Filing Date: 12/30/2003	Group Art Unit: Not Yet Known
<p>173. Wood, R.W. et al. (1996). "Generation of Stable Test Atmospheres of Cocaine Base and Its Pyrolyzate, Methylecgonidine, and Demonstration of Their Biological Activity." <i>Pharmacology Biochemistry & Behavior</i>. 55(2):237-248.</p>			
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FORM PTO-14 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Docket Number: 00029.10 CON	Application Number: 10/750,303
		Applicant: Joshua D. RABINOWITZ et al. Filing Date: 12/30/2003 Group Art Unit: Not Yet Known	

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	2.	02/02/1971	3,560,607	Hartley et al.			
	3.	01/15/1980	4,183,912	Rosenthal			
	4.	05/27/1980	Re. 30,285	Babington			
	5.	01/23/1990	4,895,719	Radhakrishnun et al.			
	6.	09/17/1991	5,049,389	Radhakrishnun			
	7.	02/14/1995	5,388,574	Ingebrethsen			
	8.	08/13/1996	5,544,646	Lloyd et al.			
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	85.	1/16/2003	US 2003/0012740	Rabinowitz et al.			
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	115.	08/12/2004	US 2004/0156789	Rabinowitz et al.				
	116.	8/12/2004	US 2004/0156790	Rabinowitz et al.				

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	119.	08/29/2001	EP 0 606 486	Europe			
	120.	04/11/1996	WO 96/09846	WIPO			
	121.	05/09/1996	WO 96/13161	WIPO			
	122.	05/09/1996	WO 96/13290	WIPO			
	123.	05/09/1996	WO 96/13291	WIPO			
	124.	05/09/1996	WO 96/13292	WIPO			
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	126.	08/07/1997	WO 97/27804	WIPO			
	127.	10/02/1997	WO 97/35562	WIPO			
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	138.	09/17/2000	WO 00/47203	WIPO			
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	156.	Gonda,I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.

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157.	Hatsukami D, et al. (May 1990) "A method for delivery of precise doses of smoked cocaine-base to humans." <i>Pharmacology Biochemistry & Behavior</i> . 36(1):1-7.
158.	Heyder, J. et al. (1986). "Deposition of Particles in the Human Respiratory Tract in the Size Range 0.005-15 µm," <i>J. Aerosol Sci.</i> 17(5):811-822.
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U.S. PATENT DOCUMENTS

Examiner Initials	Ref No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	09/01/1959	2,902,484	Horclois			
	2.	02/02/1971	3,560,607	Hartley et al.			
	3.	01/15/1980	4,183,912	Rosenthal			
	4.	05/27/1980	Re. 30,285	Babington			
	5.	01/23/1990	4,895,719	Radhakrishnun et al.			
	6.	09/17/1991	5,049,389	Radhakrishnun			
	7.	02/14/1995	5,388,574	Ingebrethsen			
	8.	08/13/1996	5,544,646	Lloyd et al.			
	9.	12/09/1997	5,694,919	Rubsamen et al.			
	10.	04/07/1998	5,735,263	Rubsamen et al.			
	11.	04/14/1998	5,738,865	Baichwal et al.			
	12.	06/02/1998	5,758,637	Ivri et al.			
	13.	06/29/1999	5,915,378	Lloyd et al.			
	14.	08/10/1999	5,934,272	Lloyd et al.			
	15.	09/28/1999	5,957,124	Lloyd et al.			
	16.	10/05/1999	5,960,792	Lloyd et al.			
	17.	11/30/1999	5,993,805	Sutton et al.			
	18.	03/28/2000	6,041,777	Faithfull et al.			
	19.	04/18/2000	6,051,566	Bianco			
	20.	08/01/2000	6,095,134	Sievers et al.			
	21.	08/01/2000	6,095,153	Kessler et al.			
	22.	08/15/2000	6,102,036	Slutsky et al.			
	23.	06/05/2001	6,241,969	Saidi et al.			
	24.	07/03/2001	6,255,334	Sands			
	25.	10/09/2001	6,299,900	Reed, et al.			

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26.	04/23/2002	6,376,550	Raber et al.			
27.	07/16/2002	6,420,351	Tsai et al.			
28.	01/14/2003	6,506,762	Horvath et al.			
29.	02/04/2003	6,514,482	Bartus et al.			
30.	07/15/2003	6,591,839	Meyer et al.			
31.	09/06/2001	US 2001/0020147	Staniforth et al.			
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33.	05/16/2002	US 2002/0058009	Bartus et al.			
34.	07/04/2002	US 2002/0086852	Cantor			
35.	08/22/2002	US 2002/0112723	Schuster et al.			
36.	11/28/2002	US 2002/0176841	Barker et al.			
37.	01/02/2003	US 2003/0004142	Prior et al.			
38.	02/13/2003	US2003/0032638	Kim et al.			

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39.	08/04/2003	10/633,876	Hale et al.			
40.	08/04/2003	10/633,877	Hale et al.			
41.	12/30/2003	10/749,537	Rabinowitz et al.			
42.	12/30/2003	10/749,539	Rabinowitz et al.			
43.	01/27/2004	10/766,149	Rabinowitz et al.			
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52.	01/29/2004	10/768,281	Rabinowitz et al.			
53.	01/29/2004	10/768,293	Rabinowitz et al.			
54.	01/30/2004	10/769,046	Rabinowitz et al.			

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55.	01/30/2004	10/769,051	Rabinowitz et al.		
56.	01/29/2004	10/769,157	Rabinowitz et al.		
57.	01/29/2004	10/769,197	Rabinowitz et al.		
58.	02/09/2004	10/775,583	Rabinowitz et al.		
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61.	03/03/2004	10/792,001	Rabinowitz et al.		
62.	03/03/2004	10/792,012	Hale et al.		
63.	03/03/2004	10/792,013	Rabinowitz et al.		
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72.	04/01/2004	10/816,492	Rabinowitz et al.		
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78.	01/02/2003	US 2003/0000518	Rabinowitz et al.		
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83.	01/16/2003	US 2003/0012737	Rabinowitz et al.		
84.	01/16/2003	US 2003/0012738	Rabinowitz et al.		

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85.	1/16/2003	US 2003/0012740	Rabinowitz et al.			
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90.	01/23/2003	US 2003/0017116	Rabinowitz et al.			
91.	01/23/2003	US 2003/0017117	Rabinowitz et al.			
92.	01/23/2003	US 2003/0017118	Rabinowitz et al.			
93.	01/23/2003	US 2003/0017119	Rabinowitz et al.			
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96.	01/30/2003	US 2003/0021754	Rabinowitz et al.			
97.	01/30/2003	US 2003/0021755	Hale et al.			
98.	02/20/2003	US 2003/0035776	Hodges et al.			
99.	05/15/2003	US 2003/0091511	Rabinowitz et al.			
100.	05/27/2004	US 2004/010148	Hale et al.			
101.	07/31/2003	US 2003/0138382	Rabinowitz			
102.	11/06/2003	US 2003/0206869	Rabinowitz et al.			
103.	01/15/2004	US 2004/0009128	Rabinowitz et al.			
104.	05/20/2004	US 2004/0096402	Hodges et al.			
105.	05/27/2004	US 2004/0099269	Hale et al.			
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107.	06/03/2004	US 2004/0105819	Hale et al.			
108.	07/01/2004	US 2004/0126326	Rabinowitz et al.			
109.	07/01/2004	US 2004/0126327	Rabinowitz et al.			
110.	07/01/2004	US 2004/0126328	Rabinowitz et al.			
111.	07/01/2004	US 2004/0126329	Rabinowitz et al.			
112.	07/01/2004	US 2004/0127481	Rabinowitz et al.			
113.	07/01/2004	US 2004/0127490	Rabinowitz et al.			
114.	08/12/2004	US 2004/0156788	Rabinowitz et al.			

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	115.	08/12/2004	US 2004/0156789	Rabinowitz et al.			
	116.	8/12/2004	US 2004/0156790	Rabinowitz et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	117.	03/14/1990	EP 0 358 114	Europe			
	118.	07/03/2001	EP 1 080 720	Europe			
	119.	08/29/2001	EP 0 606 486	Europe			
	120.	04/11/1996	WO 96/09846	WIPO			
	121.	05/09/1996	WO 96/13161	WIPO			
	122.	05/09/1996	WO 96/13290	WIPO			
	123.	05/09/1996	WO 96/13291	WIPO			
	124.	05/09/1996	WO 96/13292	WIPO			
	125.	10/03/1996	WO 96/30068	WIPO			
	126.	08/07/1997	WO 97/27804	WIPO			
	127.	10/02/1997	WO 97/35562	WIPO			
	128.	05/28/1998	WO 98/22170	WIPO			
	129.	07/23/1998	WO 98/31346	WIPO			
	130.	08/27/1998	WO 98/36651	WIPO			
	131.	04/08/1999	WO 99/16419	WIPO			
	132.	12/16/1999	WO 99/64094	WIPO			
	133.	01/06/2000	WO 00/00176	WIPO			
	134.	01/06/2000	WO 00/00215	WIPO			
	135.	05/18/2000	WO 00/27363	WIPO			
	136.	05/18/2000	WO 00/27359	WIPO			
	137.	05/25/2000	WO 00/29053	WIPO			

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**INFORMATION DISCLOSURE CITATION
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(Use several sheets if necessary)

138.	09/17/2000	WO 00/47203	WIPO			
139.	11/02/2000	WO 00/64940	WIPO			
140.	11/09/2000	WO 00/66084	WIPO			
141.	11/09/2000	WO 00/66206	WIPO			
142.	12/21/2000	WO 00/76673	WIPO			
143.	01/25/2001	WO 01/05459	WIPO			
144.	03/01/2001	WO 01/13957	WIPO			
145.	06/14/2001	WO 01/41732	WIPO			
146.	12/20/2001	WO 01/95903	WIPO			
147.	03/28/2002	WO 02/24158	WIPO			
148.	03/28/2002	WO 02/24158	WIPO			

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(including author, title, Date, Pertinent Pages, Etc.)

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	149.	Bennett, R.L. et al. (1981). "Patient-Controlled Analgesia: A New Concept of Postoperative Pain Relief," <i>Annual Surg.</i> 195(6):700-705.
	150.	Carroll, M.E. et al. (1990), "Cocaine-base smoking in rhesus monkeys: reinforcing and physiological effects," <i>Psychopharmacology (Berl)</i> . 102:443-450.
	151.	Clark, A. and Byron, P. (1986). "Dependence of Pulmonary Absorption Kinetics on Aerosol Particle Size," <i>Z. Erkrank.</i> 166:13-24.
	152.	Darquenne, C. et al. (1997). "Aerosol Dispersion in Human Lung: Comparison Between Numerical Simulations and Experiments for Bolus Tests," <i>American Physiological Society</i> . 966-974.
	153.	Davies, C.N. et al. (May 1972). "Breathing of Half-Micron Aerosols," <i>Journal of Applied Physiology</i> . 32(5):591-600.
	154.	Dershwitz, M., M.D., et al. (September 2000). "Pharmacokinetics and Pharmacodynamics of Inhaled versus Intravenous Morphine in Healthy Volunteers," <i>Anesthesiology</i> . 93(3): 619-628.
	155.	Finlay, W.H. (2001). "The Mechanics of Inhaled Pharmaceutical Aerosols", Academic Press: San Diego Formula 2.39. pp.3-14 (Table of Contents). pp. v-viii.
	156.	Gonda,I. (1991). "Particle Deposition in the Human Respiratory Tract," Chapter 176, <u>The Lung: Scientific Foundations</u> . Crystal R.G. and West, J.B. (eds.), Raven Publishers, New York. pp. 2289-2294.

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